

Supplementary material

Supplementary Table 1. Limit of blank results

<u>LoB</u>		Day 1		Day 2		Day 3	
Expect results	Method	Sample 1	Sample 2	Sample 1	Sample 2	Sample 1	Sample 2
		Result (ng/L)	Result (ng/L)	Result (ng/L)	Result (ng/L)	Result (ng/L)	Result (ng/L)
≤ 0.5 ng/L	TnIH	< 0	0.18	0.24	0.13	< 0	< 0
		< 0	< 0	0.31	0.08	0.10	0.06
		< 0	< 0	0.30	< 0	0.14	< 0
		0.55	0.15	0.06	< 0	0.35	0.13

Per CLSI, LoB is verified if at least 86% of samples are less than or equal to LoB. 96% < 0.5 ng/L – verified. LoB – limit of blank. TnIH – Atellica IM High-Sensitivity Troponin I assay. CLSI – Clinical and Laboratory Standards Institute.

Supplementary Table 2. Limit of detection results

<u>LoD</u>		Day 1		Day 2		Day 3	
Expect results	Method	Sample 1	Sample 2	Sample 1	Sample 2	Sample 1	Sample 2
		Result* (ng/L)	Result* (ng/L)	Result (ng/L)	Result (ng/L)	Result (ng/L)	Result (ng/L)
≥0.5 ng/L	TnIH	4.77	4.38	1.60	1.41	1.50	1.96
		3.75	4.92	0.98	1.87	1.75	2.16
		4.26	5.08	1.66	2.71	2.34	2.01
		4.51	4.38	2.08	1.71	1.60	1.61

*The target concentration determined for the LoD sample prior to testing was 1.6 ng/L. Mean LoD results from testing were 2.72 ng/L. Due to a calibration performed during the study, mean results for day 1 were 4.51 ng/L while mean results on days 2 and 3 were 1.8 ng/L. Per CLSI, LoD is verified if at least 86% of samples are greater than or equal to LoB. 100% > 0.5 ng/mL – verified. LoD – limit of detection. CLSI – Clinical and Laboratory Standards Institute. TnIH – Atellica IM High-Sensitivity Troponin I assay.

Supplementary Table 3. Limit of quantitation results

Sample 1									
1		2		3		4		5	
ng/L	Calc. result	ng/L	Calc. result	ng/L	Calc. result	ng/L	Calc. result	ng/L	Calc. result
<2.50	1.93	2.51	2.51	<2.50	2.31	<2.50	2.32	2.76	2.76
2.53	2.53	<2.50	2.39	<2.50	2.27	2.63	2.63	<2.50	2.44
<2.50	2.19	<2.50	2.33	<2.50	1.90	<2.50	2.35	<2.50	2.10
<2.50	2.47	<2.50	2.22	<2.50	2.24	<2.50	2.26	<2.50	2.20
<2.50	2.14	<2.50	2.15	<2.50	2.48	<2.50	2.45	2.60	2.60
Sample 2									
1		2		3		4		5	
ng/L	Calc. result	ng/L	Calc. result	ng/L	Calc. result	ng/L	Calc. result	ng/L	Calc. result
<2.50	2.2	<2.50	2.25	2.60	2.60	<2.50	1.86	<2.50	2.13
<2.50	2.45	<2.50	2.37	<2.50	2.33	<2.50	1.95	2.55	2.55
2.79	2.79	<2.50	2.49	2.69	2.69	2.54	2.54	<2.50	2.34
2.52	2.52	<2.50	2.27	<2.50	2.27	<2.50	2.22	<2.50	2.49
<2.50	1.91	<2.50	2.27	<2.50	2.44	2.58	2.58	2.66	2.66

Per CLSI, greater than 86% of samples need to be within the acceptable range. Target value for sample = 2.5 ng/L, $\pm 20\%$ (claimed accuracy of LoQ). Acceptable range = 2.0–3.0 ng/L. Sample 1 = 23/25 = 0.92. Sample 2 = 22/25 = 0.88. Total 45/50 = 0.90. Acceptable range – 2.0–3.0 ng/L (*i.e.*, 2.5 ng/L $\pm 20\%$). LoQ – Limit of quantitation.

Calc. result – Calculated result in ng/L. CLSI – Clinical and Laboratory Standards Institute. LoQ – Limit of quantitation.